DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d1943b

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/769-3010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our ref: 2950881

July 21, 1998

Deborah Sorgnard
President
Matrix Biokinetics, Inc.
4208 Arcata Way, Suite C
North Las Vegas, NV 89030

Dear Ms. Sorgnard::

An inspection was conducted between May 22 and June 1, 1998 of your company, Matrix Biokinetics, Inc., 4208 Arcata Way, Suite C, North Las Vegas, NV 89030, by Investigator Douglas W. Gronski. He determined that the facility manufactures and distributes an electrical muscle stimulator named the ProElecDT2. This product is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act.

The inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with either the Good Manufacturing Practice Regulation (GMPs) or the Quality Systems Requirements (QSRs) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

1. Matrix Biokinetics does not maintain the required portions of the Device History Record which reflect those operations performed at the location inspected, namely, addition of accessories, packaging and labeling. Resultant of this lack of such a record, there are no written acceptance criteria for the device. In addition, Matrix does not maintain records which reflect the results of the testing which is done on the devices by Matrix; these tests reportedly demonstrate compatibility with the Vaso Pulse. [21 CFR 820.184, 820.120. 820.80]

2. Although Matrix has written procedures for handling complaints and MDRs, they are not

followed. During the inspection, complaint handling documentation was reviewed. The review revealed, among other problems, that complete information from the complainant is not always obtained, complaint investigations which should involve the contract manufacturer are not always conducted, and there is little evaluation to determine whether a complaint meets the criteria of a reportable event under 21 CFR 803 or 804. [21 CFR 820.198]

3. Matrix does not have in place a system for qualification of its vendor/contract manufacturer [redacted], which assembles the ProElecDT2. There does not appear to have been evaluation of this vendor for suitability in compliance with quality requirements. Additionally, the extent of control to be exercised over the services of [redacted] by Matrix has not been defined. [21 CFR 820.50]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued at the conclusion of the inspection to Mr. William H. Knudson, General Counsel and Quality Assurance Manager for Matrix, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed withing 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to the following:

Andrea P. Scott
Compliance Officer
U. S. Food and Drug Administration
96 North Third St.
San Jose, CA 95112

Sincerely yours,

Charles D. Moas
Acting District Director

for Patricia C. Ziobro
Director
San Francisco District

cc: William H. Knudson
General Counsel
4208 Arcata Way, Suite C
North Las Vegas, NV 89030